Appendix E: Summary of Safety and Effectiveness Data

K002884

I. General Information

DEC - 4 2000

Company :	Fotona d.d. Stegne 7, 1210 Ljubljana, Slovenia
Contact Person :	Mojca Valjavec
Preparation Date :	08-21-00
Device Trade Name :	Paradigm-Fotona YAPLase Nd:YAP Laser System and Accessories
Common Name :	Nd:YAP Pulsed Surgical Laser System
Classification Name :	Instrument, Surgical, Powered, Laser 79-GEX 21 CFR 878-48

II. Description

The Paradigm-Fotona YAPLase system is based on Nd:YAP laser technology. Within the system, an optical cavity contains the Nd:YAP crystal, which is activated by means of the use of flashlamps. After the cavity, a red diode aiming beam is reflected onto a coaxial beam path using a beamsplitter assembly. The combined therapuetic and aiming beams are guided down an optical fiber delivery system to a focusing handpiece. The laser is used in non-contact mode.

The YAPLase system is designed with 5 major sub-systems:

a) A high voltage power supply which converts and rectifies the a.c. mains current to provide regulated power for the flashlamp simmer current and main triggering pulse.

b) A cooling system consisting of an internal water flow circuit together with water-to-air heat exchanger.

c) An Nd:YAP laser rod, capable of generating optical pulses at a frequency up to 10 Hz.

d) An optical delivery system, interfacing the energy from the laser to the patient via an optical fiber and focusing handpiece.

e) The microprocessor based controller which regulates the functions of the laser and allows parameter selection by the user.

II. Intended Use

The Paradigm-Fotona YAPLase Nd:YAP Laser System is indicated for incision, ablation, vaporization, and coagulation of soft tissue in various surgical areas.

III. Summary of Substantial Equivalence

Fotona believes that its YAPLase system is substantially equivalent to the Depilase YAGLASE Nd:YAG Laser (K000106), and other Nd:YAG lasers previously cleared for incision, ablation, vaporization, and coagulation of soft tissue in various surgical areas.

The Depilase YAGLASE is cleared for incision, ablation, vaporization, and coagulation of soft tissue in various surgical areas. It therefore has the same Intended Use as the Paradigm-Fotona YAPLase Laser System..

Technologically, the predicate device has completely identical characteristics to the YAPLASE, except the laser rod. Both systems comprising a flashlamp pumped laser rod (either Nd:YAG or Nd:YAP) generating light at a wavelength of 1064 nm (Nd:YAG) or 1079 nm (Nd:YAP), which is subsequently delivered to the patient via an optical fiber delivery system and focusing handpiece. The Paradigm YAPLASE and Depilase YAGLASE share the same handpieces (2, 3, 4, and 6 mm spot size).

The YAPLase Laser output characteristics are identical to those of predicate device.

Both lasers are microprocessor controlled devices.

Both lasers utilize class I aiming beams which pose no hazard to the user.

Both systems utilize an internal closed loop water-air heat exchanger circuit for optimal thermal control of the laser cavity.

The risk and benefits for the Paradigm-Fotona YAPLase are comparable to the predicate device when used for similar clinical applications.

It is therefore believed that there are no new questions of Safety or Effectiveness raised by the introduction of this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 4 2000

Mr. Mojca Valjavec
Laser Division
Fotona d.d.
Stegne 7
1210 Ljubljana, Slovenia

Re: K002884
Trade Name: Paradigm-Fotona YAPLase Nd:YAP Laser System and Accessories
Regulatory Class: II
Product Code: GEX
Dated: September 12, 2000
Received: September 15, 2000

Dear Mr. Valjavec:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPENDIX F

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K002884

Device Name: **PARADIGM YAPLase Nd:YAP LASER SYSTEM**

Indications For Use:

The Paradigm-Fotona YAPLase Nd:YAP Laser System and Accessories are intended for incision, ablation, vaporization, and coagulation and hemostasis of vascular lesions and soft tissue in various surgical areas.

Dermatology: Photocoagulation of pigmented lesions to reduce lesion size

Plastic Surgery: Coagulation and vaporization of soft tissue.

Otorhinolaryngology / Head and Neck (ENT): Tissue ablation and vessel hemostasis.

Hemostasis during Surgery: Adjunctive coagulation and hemostasis (bleeding control) during surgery in endoscopic (e.g. laparoscopic) and open procedures.

Orthopedics: Ablation, vaporization, incision, excision, coagulation, and hemostasis of soft and cartilaginous tissue in small and large joints including but not limited to knee meniscectomy, knee synovectomy, chondromaliacia and tears, shoulder debridement of scar tissue, and synovectomy of the shoulder.

Neurosurgery: Hemostasis in neurosurgery procedures such as excision of brain lesions, spinal cord lesions, cranial nerves, peripheral nerves, and pituitary glands.

Gastroenterology: Tissue ablation and hemostatsis in the gastrointestinal tract; esophageal neoplastic obstructions including squamous cell carcinoma and adenocarcinoma;
Gastrointestinal hemostasis including varices, espohagitis, esopageat ulcer, Mallory-Weiss tear, gastric ulcer, stomach ulcers, angiodysplasia, non-bleeding ulcers, gastric erosions;
Gastrointestinal tissue ablation including benign and malignant neoplasm, angiodysplasia, polyps, ulcer, colitis, hemorroids.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkerson

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K002884

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)